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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,905	03/04/2004	Yi Li	1488.115000P	3954

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EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/791,905	LI ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/25/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) Claims 1 to 9 are pending in the instant application.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claims 1 to 9 stand rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 4 of the office action mailed 25 November of 2005. As stated therein, the instant claims are drawn to an antibody that binds to an epitope contained within a protein identified in the instant specification as "HDGNR10". Beyond the assertion that "HDGNR10" is a putative member of the chemokine receptor family, the instant application does not disclose a **specific** biological role for this protein or its established significance to a particular disease, disorder of physiological process which one would wish to manipulate for a desired clinical effect.

Applicant has traversed this rejection on the premise that "[c]ontrary to what the Examiner suggests, Applicants need not confirm any asserted utility" and that "Applicants need only to assert one specific utility of the claimed invention; all aspects of the claimed utility are not required to be proven". Actually, Applicant must disclose at least one specific and substantial **credible** utility for the claimed invention **in its currently available form**. Applicant is advised that a statement of a specific utility is treated as true if it would be believed to be true by one of ordinary skill in the art given the evidence of record. Because there is absolutely no evidence provided by the instant

specification or the prior art of record that a receptor protein of the instant invention is involved in any specific way with all of the plurality of causally unrelated disorders that are listed on page 22 of the instant specification, the utilities asserted therein are not credible to one of ordinary skill in the art of receptor biology in view of the evidence of record, or more precisely, the lack thereof.

Applicant's position that the USPTO is obligated to unquestionably accept any and all statements of fact in a patent application, irrespective of whether those statements are supported by any facts of record or sound scientific reasoning is erroneous. "Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant 's assertions", (M.P.E.P. 2106.02 II(b)(1)(ii)).

Because one of ordinary skill would not reasonably conclude that every chemokine receptor is involved in every aspect of every inflammatory condition, as shown by the text in paragraphs 0009 and 0010 of the instant specification, Applicant leaves it to the artisan to identify those processes that are actually mediated by the activation of a HDGRN10 protein of the instant invention. An invention lacks specific and substantial utility in currently available form when additional experimentation is required to identify or reasonably confirm a specific and substantial utility.

Further, the instant application fails to credibly identify a specific disease or disorder that could be treated by the administration of a fragment of the claimed protein or an antibody thereto, as asserted in paragraphs 0089 and 0092 therein. It has been

well established in the art, as shown by the text on pages 22 and 23 of the Chuntharapai et al. publication (METHODS IN ENZYMOLOGY 288:15-27, 1997) that the production of therapeutic (blocking) antibodies to chemokine receptors required knowledge of the identity of at least one agonist thereto, and the instant specification fails to provide such information. Therefore, one could not have used a protein of the instant invention in the identification of useful agonist or antagonists thereto by following the guidance in the instant specification without the need to make a substantial further inventive contribution.

Applicant urges that "even assuming, arguendo, that the remainder of the asserted uses lack credibility, the assertion regarding rheumatoid arthritis is sufficient to fulfill the requirement under 35 U.S.C § 101". The assertion of multiple utilities for a claimed compound in an application does not constitute the assertion of a specific and substantial credible utility when one would not reasonably expect, based upon the evidence of record, that the claimed compound has most, if not all, of the asserted utilities and where it is clear that a specific and substantial utility has not been established for the claimed invention. In essence, such a list constitutes nothing more than a shopping list from which Applicant hopes that one or more of the listed utilities will ultimately be proven. In the case of *In re Gottlieb*, 140 USPQ 665, 668 (CCPA 1964) the compound in question had **proven** antibiotic activity and the additional asserted utilities were additional to that single, **established** specific and substantial utility.

Applicant urges that the publication of Suzuki et al. found that "T cells expressing CCR5 selectively accumulate in the inflamed joints of patients with rheumatoid arthritis". This discovery is in direct conflict with the text in paragraph 0016 of the instant specification, which states that "[I]n accordance with still another embodiment of the present invention there are provided processes of administering compounds to a host **which bind to and activate** the receptor polypeptide of the present invention which are useful in stimulating haematopoiesis, wound healing, coagulation, angiogenesis, to treat solid tumors, chronic infections, leukemia, **T-cell mediated auto-immune diseases**, parasitic infections, psoriasis, and to stimulate growth factor activity" (emphasis added). It is now known that the CC chemokines macrophage inflammatory protein-1α (MIP-1α), macrophage inflammatory protein-1β (MIP-1β), and RANTES, are all inflammatory agents that bind to and activate a receptor polypeptide of the instant invention. Given the post-filing discovery that a protein of the instant invention is a receptor that induces macrophage response to these inflammatory agents, it is unclear how they can be used to stimulate "haematopoiesis, wound healing, coagulation, angiogenesis, to treat solid tumors, chronic infections, leukemia, T-cell mediated auto-immune diseases, parasitic infections, psoriasis, and to stimulate growth factor activity" as asserted in the instant specification. Rheumatoid arthritis appears to be a well known and extensively studied T-cell mediated auto-immune disease but the art of record does not seem to disclose or suggest the treatment of this disease by the administration of those inflammation-inducing compounds MIP-1α, MIP-1β, and RANTES, which are also well known in the art. In essence, the instant specification expressly taught that **agonists** of the claimed

protein could be administered for the treatment of T-cell mediated autoimmune diseases, an assertion that the subsequent art has shown to be false.

Further, even if one went so far as to conclude that an inflammatory response was mediated by the agonist activation of a protein of the instant invention, as the subsequent art supports, that protein still lacked specific utility in currently available form because one could not identify an antagonist thereto until one has first identified an agonist, and this additional inventive contribution was required before the claimed invention had practical utility in the identification of anti-inflammatory agents.

5) Claims 1 to 9 are rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

6) Claim 8 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. As stated in the previous office action, this claim requires the antibody recited therein to be "an antagonist of the polypeptide of SEQ ID NO:2". An antagonist to a receptor protein, by definition, is an agent that inhibits the activation of that receptor by an agonist. To produce an antibody having the antagonistic activity recited in this claim, one must be able to measure the ability of an antibody to inhibit the agonist activation of a protein having the amino acid sequence of SEQ ID NO:2.

Applicant has traversed this rejection on the basis that the Lin et al. abstract described the production of antagonistic antibodies to CD2 in the absence of a knowledge of the identity of an agonist thereto. Lin et al. is irrelevant to the instant

rejection because CD2 is in no way related structurally or functionally to any member of the G protein-coupled receptor family. Applicant's attention is to the Chuntharapai et al. publication cited above, which does describe the production of antagonistic antibodies to members of the chemokine receptor family to which the HDGRN10 protein of the instant invention is alleged to belong. Table I on page 23 of that reference shows that antibodies that bind the extracellular domain of a chemokine receptor are not necessarily antagonistic thereto and the text on page 22 of that references discloses the need to employ a biological assay in the identification of blocking (antagonistic) antibodies to a particular chemokine receptor. It is unclear how one can identify a compound that inhibits the agonist activation of a chemokine receptor without being able to measure the activity being inhibited.

7) Applicant's arguments filed 25 April of 2006 have been fully considered but they are not persuasive.

8) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN ULM
PRIMARY EXAMINER
GROUP 1800